



Vitax Limited
Owen Street
LE67 3DE Coalville Leicestershire
United Kingdom

, 01.08.2018

Your ref.:
[Your ref.]

Our ref. :
2015/5844

Contact person:
Trygve Helgerud

Change to biocidal product authorisation – Nippon Maurmiddel – NO-2015-0109

We refer to your application for a change to the biocidal product authorisation for Nippon Maurmiddel – NO-2015-0109 (Case no BC-JV031784-12).

According to Article 50 (2) in Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be approved by the Competent Authority. Changes to a product authorisation are further described in Regulation (EU) No 354/2013.

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The change to Nippon Maurmiddel concerns submission of confirmatory efficacy trial data, and is classified as a major change, in accordance with the criteria laid down in Title 3 of the Annex to Regulation (EU) No. 354/2013.

Decision

Subject to Articles 19 and 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency approves the proposed change to Nippon Maurmiddel.

No other changes than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the authorisation conditions as stated in the authorisation letter dated 4 December 2015 are valid.

The revised SPC is uploaded to R4BP3. In some cases a PDF-file of the SPC is automatically generated in R4BP3. In such cases, please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file generally seems to contain some errors.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian

Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Yours sincerely,
Norwegian Environment Agency

This document has been signed electronically

Erlend Spikkerud
on behalf of
Trine-Lise Torgersen
Head of Section

Trygve Helgerud
Senior Executive Officer